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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,093	09/04/2003	Yutaka Umehara	302962 81476	6886

50670 7590 11/29/2006

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EXAMINER
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WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<p><b>Application No.</b></p> <p align="center">10/655,093</p>	<p><b>Applicant(s)</b></p> <p align="center">UMEHARA ET AL.</p>	
	<p><b>Examiner</b></p> <p align="center">Deborah K. Ware</p>	<p><b>Art Unit</b></p> <p align="center">1651</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8,10-18,20 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) 4-8, 10-18, 20, 22 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br/> Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/> Paper No(s)/Mail Date: _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|--|---|

### **DETAILED ACTION**

Claims 1, 3-8, 10-18, 20, and 22-28 are presented for reconsideration on the merits.

#### ***Response to Amendments***

The amendments filed December 12, 2005, and September 21, 2006, have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Miscellaneous Papers***

The change of address filed February 2, 2005, and power of attorney filed February 17, 2005, have been received and entered. Further, the extension of time filed December 12, 2005, has been received and entered.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 12, 2005, has been entered.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1, 3 and 23-27, in the reply filed on September 21, 2006, is acknowledged. The traversal is on the ground(s) that

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the restriction is improper because a serious burden has not been established. This is not found persuasive because the Examiner is forced to search all of the newly claimed inventions which require additional steps in their separate and distinct processes not required before and that the art as previously applied may not be applied against the newly amended claimed subject matter and added new claims upon filing of the RCE. Different classifications have subdivided the previously claimed inventions based upon the amendments in accordance with the filing of a RCE. These new classifications and amendments lead the Examiner to perform another exhaustive and continuing search of differently claimed subject matter and hence a serious burden of search is the result.

However, as indicated below claims can be rejoined at the time of indication of allowable subject matter:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

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are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-8, 10-18, 20, 22 and 28 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 21, 2006.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on February 28, 2005, was filed after the mailing date of the first office action on December 14, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

***Response to Amendment***

The amendment and extension of time filed therewith on April 7, 2005, have been received and entered. The remarks filed April 7, 2005 have also been entered of record and will be considered herein. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Badylak et al (US Patent No. 5,516,533), cited of record, note pages 3-4 of the prior Office action of December 14, 2004.

Claims are drawn to a cell culture matrix composition comprising a tissue powder derived from an intestinal segment and the composition may further comprise a medium.

Badylak et al, cited above, teach a cell culture matrix composition comprising a tissue powder derived from an intestinal segment and the composition may further comprise a medium. Note column 2, lines 45-61. The disclosed medium is water or buffered saline which may be optionally added to the composition.

The claims are identical to the disclosure of Badylak et al and are therefore, considered to be anticipated by the teachings thereof.

***Response to Arguments***

Applicant's arguments filed December 12, 2005, have been fully considered but they are not persuasive. The argument that the whole segment is required by the claims is noted, however, Applicants claims actually require a *portion* (emphasis added) of a

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whole tissue, which reads on an intestinal segment tissue as disclosed by Badylak et al. Applicants' own specification at page 5, lines 14-17, define the term "whole" to denote that the biological materials are not decellularized or digested prior to being processed into a cell support matrix. While Applicants have amended the instant claims to include full and intact organs or a portion thereof, the whole teaching of the specification clearly describes that a full and intact organ is not necessarily processed. Also the claims clearly require a portion (emphasis added) as discussed above.

The second argument with respect to the number of layers is noted, however, the art has been applied on the basis of tissue powder and not layers, per se. Thus, the argument(s) are not deemed persuasive. In addition, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Applicants' definition of "portion" in the claims is not described in the claims per se) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Thus, the argument that Badylak is not using the entire segment is noted, but not persuasive.

The cited disclosure clearly teaches that the intestine segment used to prepare the disclosed cell matrix composition does not have to be digested and is comminuted by tearing, cutting, grinding, shearing and the like, note column 2, lines 52-53. Furthermore, the open ended term "comprising" does not necessarily omit a tissue

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powder derived from intestinal segment as disclosed by Badylak et al. The "whole segment" for which Applicants argue as the claimed critical feature for their invention is clearly anticipated by Badylak et al teachings of their cell culture matrix derived from the intestinal submucosa comprising a segment of intestinal tissue, see the abstract, line 9. For these reasons and those of record Applicants' arguments are not deemed persuasive and the rejection is sustained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3 and 23-27 are rejected under 35 U.S.C. 102(a) as being anticipated by newly cited Yang, see enclosed PTO-1449 Form.

Claims are drawn to cell culture matrix composition comprising tissue powder and method for producing the tissue powder.

Yang teaches cell culture matrix composition comprising tissue powder and method for producing the tissue powder, see abstract and page 2, column 2, [0033], line 3, page 3, [0045], lines 1-30, page 6, [0084], line 5, page 7, [0087], all lines.

The claims are identical to the cited disclosure of Yang and are considered to be anticipated by these teachings therein. Yang clearly teach a segment of blood vessel from which a powder is derived as the tissue composition.



### ***Response to Arguments***

Applicant's arguments filed December 12, 2005, have been fully considered but they are not persuasive. The argument that the whole segment is required by the claims is noted, however, Applicants claims actually require a *portion* (emphasis added) of a whole tissue, which reads on an intestinal segment tissue as disclosed by Badylak et al. Applicants' own specification at page 5, lines 14-17, define the term "whole" to denote that the biological materials are not decellularized or digested prior to being processed into a cell support matrix. While Applicants have amended the instant claims to include full and intact organs or a portion thereof, the whole teaching of the specification clearly describes that a full and intact organ is not necessarily processed. Also the claims clearly require a portion (emphasis added) as discussed above.

The second argument with respect to the number of layers is noted, however, the art has been applied on the basis of tissue powder and not layers, per se. Thus, the argument(s) are not deemed persuasive. In addition, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Applicants' definition of "portion" in the claims is not described in the claims per se) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). For these reasons and those discussed above the rejection is sustained.

***Claim Rejections - 35 USC § 103***

Claims 1, 3, and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak et al, Weiss et al and Vail et al, all cited of record, for reasons set forth in prior action of December 14, 2004, see pages 6-7.

***Response to Arguments***

Applicant's arguments filed December 12, 2005, have been fully considered but they are not persuasive. The argument that Badylak et al do not teach or suggest the newly amended claims is noted. However, as discussed above, the intestinal tissue disclosed by Badylak et al is not less than a portion, and even if one of skill can optionally read and interpret the cited disclosure as Applicants have, then within the meaning of Applicants' own definition of "whole" as discussed above one of skill would have been motivated to use a portion of intestinal tissue as disclosed by Badylak et al because the reference teaches that the powder is obtained without digestion of the tissue. All that the compositions require is tissue powder, and the prior art teaches this.

Furthermore, sonication is clearly disclosed by the cited prior art secondary references and one of skill would have been motivated to use these techniques to provide for the powder form of the organ because they are disclosed to be useful for the preparation of similar products as claimed herein. However, since the process steps are not required for the patentability of the claimed product the prior art need not teach these process steps. The claims remain *prima facie* obvious over the product claims.

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All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah K. Ware  
November 22, 2006